WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-inclusion complex, formulated into a solid oral dosage form.

2. The pharmaceutical composition according to Claim 1, wherein the complex is saturated with cladribine.

3. The composition according to Claim 1 or 2, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

4. The composition according to Claim 1 or 2, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

5. The composition according to Claim 1 or 2, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

6. The composition according to any one of Claims 1 to 3, wherein the weight ratio of cladribine to amorphous cyclodextrin is from about 1:10 to about 1:16.

7. The composition according to Claim 6, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

8. The composition according to Claim 7, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

9. The composition according to Claim 7, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

10. The composition according to Claim 6, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

11. The composition according to any one of Claims 1 to 10, wherein the approximate molar ratio of cladribine to amorphous cyclodextrin corresponds to a point located on a phase solubility diagram for saturated complexes of cladribine in varying concentrations of the cyclodextrin.

12. The composition according to any one of Claims 1 to 11, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

13. A method for enhancing the oral bioavailability of cladribine comprising orally administering to a subject in need thereof a pharmaceutical composition comprising a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-inclusion complex, formulated into a solid oral dosage form.

14. The method according to Claim 13, wherein the complex is saturated with cladribine.

15. The method according to Claim 13 or 14, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

16. The method according to Claim 13 or 14, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

17. The method according to Claim 13 or 14, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

18. The method according to any one of Claims 13 to 15, wherein the weight ratio of cladribine to amorphous cyclodextrin is from about 1:10 to about 1:16.

19. The method according to Claim 18, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

20. The method according to Claim 19, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

21. The method according to Claim 19, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

22. The method according to Claim 18, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

23. The method according to any one of Claims 13 to 22, wherein the approximate molar ratio of cladribine to amorphous cyclodextrin

corresponds to a point located on a phase solubility diagram for saturated complexes of cladribine in varying concentrations of the cyclodextrin.

24. The method according to any one of Claims 13 to 23, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

25. A method for the treatment of symptoms of a cladribine-responsive condition in a subject suffering from said symptoms comprising orally administering to said subject a pharmaceutical composition comprising a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-inclusion complex, formulated into a solid oral dosage form.

26. The method according to Claim 25, wherein the complex is saturated with cladribine.

27. The method according to Claim 25 or 26, wherein the cladribine-responsive condition is selected from the group consisting of multiple sclerosis, rheumatoid arthritis and leukemia.

28. The method according to Claim 27, wherein the cladribine-responsive condition is multiple sclerosis.

29. The method according to Claim 25, 26, 27 or 28, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin,

hydroxypropyl-γ-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

30. The method according to any one of Claims 25 to 29, wherein the weight ratio of cladribine to amorphous cyclodextrin is from about 1:10 to about 1:16.

31. The method according to any one of Claims 25 to 30, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

32. The method according to Claim 31, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

33. The method according to Claim 31, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

34. The method according to Claim 25, 26, 27 or 28, wherein the amorphous cyclodextrin is hydropropyl-γ-cyclodextrin.

35. The method according to any one of Claims 25 to 34, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

36. Use of a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-inclusion complex, in the formulation of a solid oral dosage form, for administration in the treatment of symptoms of a cladribine-responsive condition.

37. Use according to Claim 36, wherein the complex is saturated with cladribine.

38. Use according to Claim 36 or 37, wherein the cladribine-responsive condition is selected from the group consisting of multiple sclerosis, rheumatoid arthritis and leukemia.

39. Use according to Claim 38, wherein the cladribine-responsive condition is multiple sclerosis.

40. Use according to Claim 36, 37, 38 or 39, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

41. Use according to any one of Claims 36 to 40, wherein the weight ratio of cladribine to amorphous cyclodextrin is from about 1:10 to about 1:16.

42. Use according to any one of Claims 36 to 41, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

43. Use according to Claim 42, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

44. Use according to Claim 42, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

45. Use according to any one of Claims 36 to 41, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

46. Use according to any one of Claims 36 to 45, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

47. Use of a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-inclusion complex, in the formulation of a solid oral dosage form, for enhancing the oral bioavailability of cladribine.

48. Use according to Claim 47, wherein the complex is saturated with cladribine.

49. Use according to Claim 47 or 48, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

50. Use according to any one of Claims 47 to 49, wherein the weight ratio of cladribine to amorphous cyclodextrin is from about 1:10 to about 1:16.

51. Use according to any one of Claims 47 to 50, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

52. Use according to Claim 51, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

53. Use according to Claim 51, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

54. Use according to any one of Claims 47 to 50, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

55. Use according to any one of Claims 47 to 54, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

56. A complex cladribine-cyclodextrin complex which is an intimate amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-inclusion complex.

57. The complex according to Claim 56, saturated with cladribine.

58. The complex according to Claim 56 or 57, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

59. The complex according to Claim 56 or 57, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

60. The complex according to Claim 56 or 57, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

61. The complex according to any one of Claims 56 to 58, wherein the weight ratio of cladribine to amorphous cyclodextrin is from about 1:10 to about 1:16.

62. The complex according to Claim 61, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

63. The complex according to Claim 62, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

64. The complex according to Claim 62, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

65. The complex according to Claim 61, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

66. The complex according to any one of Claims 56 to 65, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

67. A process for the preparation of a complex cladribine-cyclodextrin complex which comprises the steps of:

(i) combining cladribine and an amorphous cyclodextrin in water at a temperature of from about 40 to about 80°C and maintaining said temperature for a period of from about 6 to about 24 hours;

(ii) cooling the resultant aqueous solution to room temperature; and

(iii) lyophilizing the cooled solution to afford an amorphous product.

68. A process according to Claim 67, further comprising a filtration step following step (ii).

69. A process according to Claim 67 or 68, wherein step (i) is performed at a temperature of from about 45 to about 60°C.

70. A process according to any one of Claims 67 to 69, wherein step (i) is performed at a temperature of from about 45 to about 50°C.

71. A process according to Claim 69 or 70, wherein step (i) is performed with stirring.

72. A process according to Claim 71, wherein step (i) is performed for a period of from about 6 to about 9 hours.

73. A process according to any one of Claims 67 to 72, wherein step (ii) is performed for a period of from about 6 to about 9 hours.

74. A process according to any one of Claims 67 to 73, wherein step (iii) comprises an initial freezing stage in which the solution is cooled to from about -40 to about -80° C, and held at said temperature for a period of from about 2 to about 4 hours.

75. A process according to Claim 74, wherein, in the initial freezing stage of step (iii), the solution is cooled to about -45°C.

76. A process according to any one of Claims 67 to 75, wherein 12.00 parts by weight of cladribine and 172.50 parts by weight of hydroxypropyl-β-cyclodextrin are introduced in step (i).

77. A process according to any one of Claims 67 to 75, wherein 16.35 parts by weight of cladribine and 172.50 parts by weight of hydroxypropyl-β-cyclodextrin are introduced in step (i).

78. A process according to Claim 76 or 77, wherein 825 parts by volume of water are introduced in step (i).

79. A process according to any one of Claims 67 to 78, wherein the lyophilization step (iii) comprises:

(a) an initial freezing stage in which the complexation solution is brought to from about -40°C to about -80°C for approximately 2 to 4 hours;

(b) a primary drying stage at about -25°C for approximately 80 to 90 hours; and

(c) a secondary drying stage at about 30°C for approximately 15 to 20 hours.

80. A process according to Claim 79, wherein stage (a) of the lyophilization is conducted at about -45°C for approximately 3 to 4 hours.

81. A process according to Claim 79 or 80, wherein stage (b) of the lyophilization is conducted under a pressure of about 100 mTorr.

82. A pharmaceutical composition obtainable by a process comprising the steps of:

(i) combining cladribine and an amorphous cyclodextrin in water at a temperature of from about 40 to about 80°C and maintaining said temperature for a period of from about 6 to about 24 hours;

(ii) cooling the resultant aqueous solution to room temperature;

(iii) lyophilizing the cooled solution to afford an amorphous product; and

(iv) formulating the amorphous product into a solid oral dosage form.

83. A pharmaceutical composition according to Claim 82, wherein the process further comprises a filtration step following step (i) or (ii).

84. A pharmaceutical composition according to Claim 82 or 83, wherein step (i) of the process is performed at a temperature of from about 45 to about 60°C.

85. A pharmaceutical composition according to any one of Claims 82 to 84, wherein step (i) of the process is performed at a temperature of from about 45 to about 50°C.

86. A pharmaceutical composition according to Claim 84 or 85, wherein step (i) of the process is performed with stirring.

87. A pharmaceutical composition according to Claim 86, wherein step (i) of the process is performed for a period of from about 6 to about 9 hours.

88. A pharmaceutical composition according to any one of Claims 82 to 87, wherein step (ii) of the process is performed for a period of from about 6 to about 9 hours.

89. A pharmaceutical composition according to any one of Claims 82 to 88, wherein step (iii) comprises an initial freezing stage in which the solution is cooled to from about -40 to about -80°C, and held at said temperature for a period of from about 2 to about 4 hours.

90. A pharmaceutical composition according to Claim 89, wherein, in the initial freezing stage of step (iii), the solution is cooled to about -45°C.

91. A pharmaceutical composition according to any one of Claims 82 to 90, wherein 12.00 parts by weight of cladribine and 172.50 parts by weight of the hydroxypropyl-β-cyclodextrin are introduced in step (i) of the process.

92. A pharmaceutical composition according to any one of Claims 82 to 90, wherein 16.35 parts by weight of cladribine and 172.50 parts by weight of the hydroxypropyl-β-cyclodextrin are introduced in step (i) of the process.

93. A pharmaceutical composition according to Claim 91 or 92, wherein 825 parts by volume of water are introduced in step (i) of the process.

94. A pharmaceutical composition according to any one of Claims 82 to 93, wherein the lyophilization step (iii) of the process comprises:

(a) an initial freezing stage in which the complexation solution is brought to from about -40°C to about -80°C for approximately 2 to 4 hours;

(b) a primary drying stage at about -25°C for approximately 80 to 90 hours; and

(c) a secondary drying stage at about 30°C for approximately 15 to 20 hours.

95. A pharmaceutical composition according to Claim 94, wherein stage (a) of the lyophilization is conducted at about -45°C for approximately 3 to 4 hours.

96. A pharmaceutical composition according to Claim 94 or 95, wherein stage (b) of the lyophilization is conducted under a pressure of about 100 mTorr.

97. A pharmaceutical composition according to any one of Claims 82 to 96, wherein the formulation step (iv) of the process comprises blending the complex with magnesium stearate and compressing into tablets.

98. A pharmaceutical composition according to Claim 97, wherein magnesium stearate is pre-mixed with sorbitol powder before blending with the complex.